REMARKS/ARGUMENTS

Claims 1, 3-9, 12, 15-19, and 22-25 are pending. Claims 26-36 stand withdrawn as being directed to a non-elected species. Applicants believe currently pending claim 1 is generic with respect to all pending dependent claims, including the withdrawn claims.

Sole independent claim 1 has been amended to more clearly distinguish the "axial slit (24)" along the catheter body (12) from the "passage (41)" of the balloon structure (14). No new matter has been added thereby.

The pending claims stand free of any rejections based upon the art of record. A Declaration by Udayan Patel under 37 C.F.R. § 1.132 filed on May 31, 2005 has also been entered into the record. Re-examination and reconsideration of pending claims 1, 3-9, 12, 15-19, and 22-36 are respectfully requested.

Examiner Interview

Applicants thank Examiner Thaler for the kind and courteous interview on November 18, 2005. Independent claim 1 was discussed in light of the 35 U.S.C. § 112, first paragraph rejection. A model of the invention was shown embodying the elements of claim 1 so as to further buttress Applicants' position that one reasonably skilled in the art at the time the application was filed could have constructed the claimed balloon catheter of claim 1 from the disclosures directed to elected Figs. 5A and 13A in the patent application, coupled with information known in the art, without undue or unreasonable experimentation.

Rejection Under 35 U.S.C. § 112

Claims 1, 3-9, 12, 15-19, and 22-25 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner asserts that:

> [t]he claims(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is it is most nearly connected, to make and/or use the invention. The embodiment of figures 5A, 5B and 13A, as described in the specification and shown in the drawings, is inoperable.

Office Action, page 2.

The test for enablement is whether one reasonably skilled in the art could make the claimed invention from the disclosures in the patent application, when filed, coupled with information known in the art without undue experimentation. M.P.E.P. § 2164.01; *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). Applicants' position is that one of ordinary skill in the art in May of 2001 could construct the disclosed invention of elected Figs. 5A and 13A such that the slidable inflation tube (26) is in communication with the balloon (40) based upon the specification and drawing of the present application coupled with information known in the art without undue or unreasonable experimentation.

Applicants have provided a Declaration by Udayan Patel under 37 C.F.R. § 1.132 filed on May 31, 2005, which has been entered into the record and is relied upon herein to support Applicants' position. Declaration, paragraphs 4-5. Mr. Patel has over fifteen years of product development experience in the medical device field, particularly in designing catheters and balloon catheters. Declaration, paragraph 1. In particular, Mr. Patel states that those of skill in the art in May of 2001 could have constructed the connection between the inflation tube and the balloon ***in many ways*** without undue or unreasonable experimentation, particularly in light of the predictability associated with the mechanical arts. Declaration, paragraph 7. Mr. Patel further provides ***one simple example*** of how to easily construct an S shaped connection based upon the patent specification and drawings. Declaration, paragraphs 8-9 and Exhibit B. As such, Applicants have clearly fulfilled the threshold for enablement as set forth above.

> The Examiner notes that:
>
> If the inner sleeve 38 is located on the outer surface of the catheter body 12, it is unclear what tube or other member connects the inflation tube 26 to the balloon. If there is such a tube, **it appears that it must be smaller in diameter than the width of the narrow portion of slit 24 shown at the outer periphery of catheter body 12** shown in figure 13A (since it must pass radially outward from inflation tube 26 to the balloon through this portion of slit 24). Yet, no tube or its dimensions are disclosed.

Office Action, page 3. Applicants emphasize that the diameter of the inflation tube (26) may be smaller or larger so as to allow for connection to the balloon (40). As illustrated during the interview with the model embodying the elements of claim 1, the material defining the catheter (12) including the axial slit (24) can be formed from several compliant materials (e.g., PBAX, PTFE, etc.) as disclosed in the originally filed application so as to allow the inflation tube (26) to emerge out of the axial slit (24) irrespective of the tube diameter. As noted on page 11, lines 16-19 of the application, "[t]he tubular catheter body may be formed from polymer materials, composite materials, braided materials, or metal materials. Typically, the tubular catheter body is formed from hypotube or as extrusions of polymeric resins. Suitable resins materials include polyamides (nylons) polyimides, polyvinylchloride, PBAX, PTFE, and the like." See also originally filed claim 6. These disclosed materials would easily allow for construction of an inflation tube (26) to be removably receivable in the axial slit (24) while substantially retaining its cross-sectional shape. This ***is yet another example*** of how the inflation tube (26) may connect to the balloon (40).

Addressing the Examiner's concerns that, "[n]o S shaped tube is disclosed" on page 4 of the Office Action, Applicants note that this point is moot as the requirements for enablement have been fulfilled. Further, the Examiner is reminded that a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991).

The Examiner further notes that, "it is not clear from the original disclosure that the tube 26 would be sufficiently flexible to make an abrupt bend out of slit 24 and make another bend to connect to the balloon 40." Office Action, page 4. Applicants note that the inflation tube (26) may be made from a variety of conventional and well known flexible and non-flexible materials, as illustrated in the model shown to the Examiner during the interview, which was formed of PBAX. Applicants' position is further bolstered by paragraph 9 in Mr. Patel's Declaration which notes that the S-shaped tube (26) may be formed from any conventional polymers or metals.

As a *prima facie* case of lack of enablement has not been established by the Examiner, Applicants respectfully request the removal of this 35 U.S.C. § 112, first paragraph

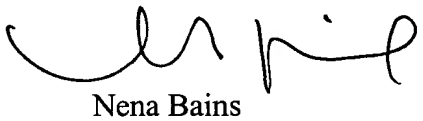
rejection, and allowance of independent claim 1 (and dependent claims 3-9, 12, 15-19, and 22-36).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Nena Bains
Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
NB:deb